DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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August 8, 2006

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 06-40

Margaret J. Larson, President
Sonotech, Incorporated
774 Marine Drive
Bellingham, Washington 98225

WARNING LETTER

Dear Ms. Larson:

On June 5-8, 2006, TUV Rheinland of North America conducted an inspection of your establishment located at 774 Marine Drive, Bellingham, Washington. This inspection was conducted on behalf of the Food and Drug Administration (FDA) under the Accredited Person Program of the Medical Device User Fee and Modernization Act of 2002. An FDA representative, Dennis Kawabata, was also present during the inspection as a Performance Auditor. This inspection has shown that your establishment markets the Ultrabio Sterile (K042619), a sterile, in-vivo biocompatible and bioeliminating ultrasound coupling gel, which is a medical device under section 201(h) [21 U.S.C. 321(h)] of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection documented significant violations of the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820. These violations cause the device you manufacture to be adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. 351(h)].

The deficiencies are as follows:

1. Where the results of a process cannot be fully verified by subsequent inspection and test, the process must be validated with a high degree of assurance and approved according to established procedures as required by 21 CFR 820.75(a).

Your firm failed to (a) include a policy in your quality manual that identifies a need for validation; and (b) establish procedures for the validation of processes; as evidenced by:

- The validation records for the heat-sealer for the Ultrabio, which includes the outer pouch ([redacted] Sealer) and the inner pouch ([redacted] fill and seal machine), did not include evidence of installation and operational qualification. Furthermore, procedures were not available for the operation of the [redacted] Sealer and the [redacted] fill and seal machine. The parameters used for the sealing of the inner pouch of the Ultrabios (recipe file "[redacted]") were not identical to or within the range of the validated parameter values [21 CFR 820.75(b)].

- The sterilization validation, [redacted] final report No. 797040212, was performed with [redacted] prototype batches, which were not manufactured under regular production conditions. No device history records were available for review.

2. Your firm failed to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets the acceptance criteria as required by 21 CFR 820.80(d). Your firm failed to define an acceptance or rejection procedure for the Ultrabio upon return from the sterilizer.

3. Your firm failed to maintain a device master record (DMR) that referred to the location of the packaging and labeling specifications, including methods and processes used, as required by 21 CFR 820.181(d), and quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used as required by 21 CFR 820.181(c). The DMR for the Ultrabio, formula control #[redacted], revision date [redacted] did not include or refer to the location of packaging and labeling procedures and specifications, or the quality assurance procedures and specification for the review of sterilization records and the final acceptance or rejection of finished devices.

4. Your firm failed to conduct quality audits by individuals who do not have the responsibility for the matters being audited as required by 21 CFR 820.22. The employees who conducted your quality audits in 2004 and 2005 do have direct responsibility for the matters being audited. Specifically, per Sonotech Quality Manual, document No. QMS.01, Section 5.5, Revision 03, the direct responsibilities of the Quality Manager includes internal audits.

5. Your firm failed to follow your own procedures for conducting quality audits as required by 21 CFR 820.22. Specifically, per Sonotech Quality Manual, document No. QMS-01, Revision 03, Monitoring and Measurements, states that defined processes shall [redacted] between audits. Your Internal Audit Plan Matrix shows "Management/Marketing" was last audited on [redacted] 2004, and the next one was rescheduled to [redacted] 2006.

6. Your firm failed to establish and maintain procedures for validating the device that include software validation and risk analysis, where appropriate, as required by 21 CFR 820.30(g). The risk analysis for the Ultrabio does not meet the requirements of procedure "Design Input Checklist & Risk Management," document No. PD-03, Revision 04. The risk analysis fails to include the analysis of the probability of occurrence of an identified hazard, the decision on whether the estimated risks are so low that risk reduction is not needed, and is not signed by the person who conducted the risk analysis.

7. Your firm failed to maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements as required by 21 CFR 820.30(d). Your design input record states that the Ultrabio is to be labeled with an expiration date. The label on the finished products for batch #5076-5077 do not include an expiration date. The risk analysis for the Ultrabio states "Endotoxins will be verified for each production run using [redacted]" This design input requirement was not included as part of your testing or production. You have produced [redacted] batches of Ultrabio, and none of them have been tested for endotoxin levels.

8. You have failed to establish and maintain procedures to control all documents as required by 21 CFR 820.40. Specifically, the document titled "Ultrabio Device Master Record," formula control No. [redacted], Revision [redacted] was found in three different versions, but all have the same revision. Furthermore, you failed to record these changes or approvals on the "Formula Revision Record," document No. W-12, Revision 03.

9. You failed to maintain your procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90. Specifically, your Ultrabio batch No. 5072 was found to contain product with "off-registration" labeling, caused by a misalignment of the printing machine. You failed to process this non-conformance per your procedure titled QMS-04, revision 04, and document it on form W-83.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the cause of the violations and take prompt action to correct the violations and to bring your product into compliance.

We acknowledge the receipt of your email dated July 7, 2006, sent to Investigator Kawabata, in which you describe some corrective actions you had taken as of that date and your plans to hire a consultant. As you are aware, your email response by itself is inadequate to address the observations because you must properly implement, document, and maintain each corrective action to ensure its effectiveness. Further, since you did not provide us any supporting documentation, we could not thoroughly evaluate what corrective actions you have taken.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to ensure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction should be included with your response to this letter.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director